K073485

MAR - 3 2008

510(k) Summary

Submitter Information

Company:	VISTAKON® Division of Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Suite 100 Jacksonville, FL 32256
Contact Person:	Rosalind Baker Williams
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Telephone:	904-403-1504
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Date Prepared:	December 11, 2007

Identification of the Device

Common Name:	Soft Contact Lens
Device Name:	VISTAKON® (narafilcon A) Contact Lens
Classification Name:	Soft Hydrophilic Contact Lens, Daily Wear
Device Classification:	Class II, 21 CFR 886.5925 (b) (1).

Predicate Device(s)

Material

VISTAKON® (galyfilcon A) Contact Lens – K032340
(FDA Group I; low water, nonionic polymer)

Indication, Wear Schedule

VISTAKON® (etafilcon) Contact Lenses – K962804
(Daily wear, single use)

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Executive Summary, Continued

Description of Device

- The VISTAKON® (narafilcon A) Contact Lens Clear and Visibility Tinted with UV blocker is available as a spherical lens, multifocal lens; toric lens, and toric-multifocal lens.
- The lenses are made of a silicone hydrogel material containing an internal wetting agent.
- The VISTAKON® (narafilcon A) Contact Lens may be tinted blue using Reactive Blue Dye #4 to make the lens more visible for handling
- A benzotriazole UV absorbing monomer is used to block UV radiation. The transmittance characteristics are less than 1% in the UVB range of 280 – 315nm and less than 10% in the UVA range of 316 – 380nm.
- The VISTAKON® (narafilcon A) Contact Lens is a hemispherical or hemitoric shell.
- The lens is supplied in a sterile state, packaged in a buffered saline solution with methyl ether cellulose.
- The composition of the lens is 54% narafilcon A and 46% water by weight when hydrated and stored in the buffered saline solution.

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510(k) Summary, Continued

Indications for Use

Lens Design	Indication
Spherical	The VISTAKON® (narafilcon A) Contact Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.
Multifocal	The VISTAKON® (narafilcon A) Contact Lens is indicated for daily wear single use only for the optical correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less.
Toric	The VISTAKON® (narafilcon A) Contact Lens is indicated for daily wear single use only for the optical correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D or less of astigmatism.
Multifocal Toric	The VISTAKON® (narafilcon A) Contact Lens is indicated for daily wear single use only for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 10.00D of astigmatism or less.

- VISTAKON® (narafilcon A) Contact Lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

- The Eye Care Professional should prescribe the lenses for daily wear single use only. The lenses are to be discarded upon removal; therefore, no cleaning or disinfecting is required.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vistakon
c/o Rosalind Baker Williams
7500 Centurion Parkway, Ste. 100
Jacksonville FL 32256

MAR - 3 2008

Re: K073485

Trade/Device Name: VISTAKON® (narafilcon A) Contact Lens for Daily Wear Single Use Only
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: December 11, 2007
Received: December 12, 2007

Dear Ms. Williams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number:

Device Name: VISTAKON® (narafilcon A) Contact Lens Clear and Visibility Tinted, with UV blocker

Indications for Use:

The VISTAKON® (narafilcon A) Soft Contact Lens (spherical) is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The VISTAKON® (narafilcon A) Multifocal Soft Contact Lens is indicated for daily wear single use only for the optical correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less.

The VISTAKON® (narafilcon A) Toric Soft Contact Lens is indicated for daily wear single use only for the optical correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D or less of astigmatism.

The VISTAKON® (narafilcon A) Multifocal-Toric Soft Contact Lens is indicated for daily wear single use only for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have 10.00D of astigmatism or less.

VISTAKON® (narafilcon A) Contact Lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.

The Eye Care Professional should prescribe the lenses for daily wear single use only. The lenses are to be discarded upon removal; therefore, no cleaning or disinfecting is required.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over the Counter** _____

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devices

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